



# Adequacy of FDA's Response to Mad Cow Disease

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# **Adequacy of FDA's Response to Mad Cow Disease**

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Food and Drug Law

## I. Introduction

The American public and the world know the problem as “Mad Cow Disease.” The challenges that arise in attempts to resolve this issue test the limits of science, government, and society. The somewhat affectionate and comical name, Mad Cow Disease, belittles the severity of this problem, which now strikes fear into the minds of the consuming public around the world. American consumers rest easy with the knowledge that they are safe because there is no evidence of the disease here; however, they may be keeping themselves blissfully ignorant. United States agencies inspire confidence by continually emphasizing that there are no cases of Bovine Spongiform Encephalopathy (BSE), the scientific name for the disease, in the United States.<sup>1</sup> However, the science does not preclude the possibility of it happening here. Actually, the most prevalent scientific theories suggest that indeed it could occur here. The question is what measures the United States needs to take in order to prevent such a development.

The Food and Drug Administration (FDA) has attempted to regulate this area in order to insure that the food supply of the United States remains safe for public consumption. However, given the uncertain state of the scientific understanding of the disease, FDA found itself in the position of trying to make decisions about the need for regulation (as well as its urgency and form) on the basis of very little conclusive information. Inevitably, the question later arises as to whether the actions that the agency took were sufficient and whether the agency took action fast enough. The American public expects that FDA will take preventative actions to protect their food supply, and they do not want to learn that this trust was misplaced from the

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<sup>1</sup>See *Petition Seeking Immediate Action by the FDA to Combat the Spread of Transmissible Spongiform Encephalopathy (TSE) in the United States*, FDA Docket Number 99P-00033, (visited Jan. 27, 1999) <<http://www.icta.org/legal/madcow1.htm>> [hereinafter *FDA Petition*].

deaths of innocent and unwitting consumers.<sup>2</sup> FDA knew that if it took effective precautionary measures, they would be criticized as unnecessary; however, if BSE is found in the United States, FDA knew that it would face criticism for not having done enough and thus would encounter the dual challenge of eliminating the disease from this country and working to regain the trust of the American people.<sup>3</sup> This dilemma was aptly expressed by a presenter at one of the open public forums discussing the proposed rule, “To FDA, I say, pursue the science but be advised, no ready or easy answers await you. You have both my respect and empathy.”<sup>4</sup> This paper will attempt to analyze the history of FDA’s response to the emergence of BSE and whether FDA’s actions were adequate to protect the American public and its food supply.

## II. Scientific Background and History of the Disease

One of the biggest problems with the quest to stop BSE or to prevent it from entering the United States is the lack of scientific certainty about the subject. Unfortunately, waiting to find some concrete answers could take too long.<sup>5</sup> So the problem is dealing with an unknown but concrete risk with only inconclusive information when the theoretical risk could be extremely large with disastrous results.<sup>6</sup>

BSE is one of a type of Transmissible Spongiform Encephalopathies (TSE’s). TSE’s are known to occur

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<sup>2</sup>See FDA, *Public Meeting for Consumers Regarding Federal Register 21 CFR Part 589 Substances Prohibited from Use in Animal Food or Food; Animal Proteins Prohibited in Ruminant Feed; Proposed Rule*, Feb. 13, 1997, p. 25 [hereinafter *Public Meeting 2*].

<sup>3</sup>See *Potential Transmission of Spongiform Encephalopathies to Humans: The Food and Drug Administration’s [FDA] Ruminant to Ruminant Feed Ban and the Safety of Other Products: Hearing Before the Comm. On Gov’t Reform and Oversight*, 105<sup>th</sup> Cong. 107 (1997) [hereinafter *1997 Hearing*] (statement of William D. Hueston, DVM, Ph.D., Univ. of Md.).

<sup>4</sup>*Public Meeting 2*, *supra* note 2, at 38.

<sup>5</sup>See *Food Safety: Oversight of the FDA Center for Veterinary Medicine: Hearing Before the Subcomm. on Human Resources and Intergovernmental Relations of the Comm. On Gov’t Reform and Oversight*, 104<sup>th</sup> Cong. 158 (1996) [hereinafter *1996 Hearing 1*] (statement of Rep. Christopher Shays, Chairman of Subcommittee).

<sup>6</sup>See *1997 Hearing*, *supra* note 3, at 1 (statement of Rep. Christopher Shays, Chairman of Subcommittee).

in humans, sheep, cows, deer and elk, mink, and can be transmitted experimentally to a number of other animals.<sup>7</sup> The TSE's in humans are kuru (found among the Fore people of New Guinea), Creutzfeldt-Jakob Disease (CJD), Gerstmann-Straussler-Scheinker disease (GSS), and fatal familial insomnia (FFI).<sup>8</sup> The mechanism behind these diseases is still not completely understood. The leading theory is that there is an infectious protein involved, a prion. The prion theory is novel because it falls outside of the central dogma of molecular biology. The normal prion protein exists naturally in many species; however, there is a difference in the conformation of the normal and infectious prion proteins.<sup>9</sup> When the infectious prion protein is introduced into a healthy animal, it is thought to induce the normal prion protein in that animal to change form.<sup>10</sup> The result is a prolonged illness affecting the central nervous system and during which the brain of the victim becomes spongy in appearance.<sup>11</sup> TSE's are always fatal and can have an incubation period of years.<sup>12</sup>

The prion theory, though the leading theory, is not accepted by all scientists. It is extremely heretical because it postulates a method of infection caused by an agent that does not carry DNA or RNA. Additionally, the body produces no immunological response, and there are often no indications of the infection until clinical signs arise.<sup>13</sup> Scientists are still investigating other theories: a spiroplasma<sup>14</sup> or a viral-like agent with nucleic acid.<sup>15</sup> Some of these scientists feel that the emphasis on the prion theory has prevented necessary debate

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<sup>7</sup>See *Bovine Spongiform Encephalopathy in the United Kingdom: Memorandum from a WHO Meeting*, 71 BULL. OF THE WORLD HEALTH ORG. 691, 691 (1993).

<sup>8</sup>See Stanley B. Prusiner, *Biology and Genetics of Prion Diseases*, 48 ANN. REV. MICROBIOLOGY 655, 655-56 (1994); *Public Health Issues Related to Animal and Human Spongiform Encephalopathies: Memorandum from a WHO Meeting*, 70 BULL. OF THE WORLD HEALTH ORG. 183, 184 (1992).

<sup>9</sup>See Prusiner, *supra* note 8, at 660-61, 675.

<sup>10</sup>See *id.* at 656.

<sup>11</sup>See *Public Health Issues Related to Animal and Human Spongiform Encephalopathies: Memorandum from a WHO Meeting*, 70 BULL. OF THE WORLD HEALTH ORG. 183 (1992)

<sup>12</sup>See *id.* at 183-84.

<sup>13</sup>See *id.* at 183.

<sup>14</sup>See *1997 Hearing*, *supra* note 3, at 109 (Frank Owen Bastion, M.D., Univ. of South Ala.).

<sup>15</sup>See *Report of a WHO Consultation on Medicinal and other Products in Relation to Human and Animal Transmissible Spongiform Encephalopathies*, WHO document WHO/EMC/ZOO/97.3 - WHO/BLG/97.2, Mar. 24-26, 1997, (last modified Apr. 24, 1998), available in <[http://www.who.int/emc/diseases/bse/tse\\_9703.html](http://www.who.int/emc/diseases/bse/tse_9703.html)> [hereinafter *WHO Report 1997*].

about the topic and misled the scientific community.<sup>16</sup> Such a mistake could greatly hinder attempts to prevent the disease from occurring, and then spreading, in the United States. Understanding the mechanism of how this agent works is especially important because it is incredibly resistant to the usual methods of inactivation.<sup>17</sup> Thus, in order to prevent the spread of the disease, information about how the infectious agent is transmitted and how to inactivate it is crucial.

BSE first emerged (to our knowledge) in the United Kingdom, where scrapie (the TSE found in sheep) is prevalent but has never before presented a problem. In the 1970s, the rendering process used to make protein supplements for animal feed was changed to remove an extraction step.<sup>18</sup> One theory to explain the emergence of the disease is that the scrapie prion was thus able to survive the rendering process and initiated the BSE epidemic through transmission in cattle feed.<sup>19</sup> Many think that the process of recycling dead cows (some of which could have had BSE), as well as sheep, into protein supplements for animal feed amplified the epidemic by spreading the BSE agent to other cows through their feed.<sup>20</sup> BSE was originally found in the United Kingdom in 1986.<sup>21</sup> On March 20, 1996, the British government announced that they had found ten new and unusual cases of CJD in the United Kingdom.<sup>22</sup> These cases were unusual because the victims died at a much earlier age than is usual for CJD, the course of the disease was longer, and the lesions in the brain were different.<sup>23</sup> This type of CJD has come to be known as new variant CJD or nv-CJD.<sup>24</sup> In Britain there are now 34 people who have nv-CJD.<sup>25</sup> In 1988, Britain took steps to prohibit this cycling of cattle back into the cattle feed.<sup>26</sup>

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<sup>16</sup>See *1997 Hearing*, *supra* note 3, at 109 (statement of Frank Owen Bastion, M.D., Univ. of South Ala.); Richard Rhodes, *Deadly Feasts* 206 (1997).

<sup>17</sup>See *WHO Report 1997*, *supra* note 15, at 5.

<sup>18</sup>See *1996 Hearing 1*, *supra* note 5, at 106-108 (statement of Frederick Murphy, School of Veterinary Medicine, Univ. of Calif., Davis).

<sup>19</sup>See *id.*

<sup>20</sup>See *id.*

<sup>21</sup>See *id.*

<sup>22</sup>See *id.*

<sup>23</sup>See *id.*

<sup>24</sup>See It is also called variant CJD (v-CJD).

<sup>25</sup>See Warren Leary, *Keeping 'Mad Cow' Away from U.S. Blood Supply*, N.Y. TIMES, Jan. 19, 1999, at D1.

<sup>26</sup>See *1996 Hearing 1*, *supra* note 5, at 112 (statement of Frederick A. Murphy, Univ. of Cal., Davis).

There is still debate about the cause of BSE. In 1988, scientists in the United Kingdom discovered an epidemiological connection between BSE and the rendered ruminant<sup>27</sup> products that are used in cattle feed.<sup>28</sup> However, epidemiological evidence may be less significant because it is circumstantial, and it cannot alone prove this link.<sup>29</sup> Another theory suggests that there are naturally occurring, undetected, spontaneous cases of BSE in a small percent of cattle.<sup>30</sup> This latter theory suggests that even if no cattle containing BSE are imported or introduced into this country, there is still the possibility that such a spontaneous case could occur and that the disease could then be disseminated through the process of rendering cattle for animal feed. There is also evidence of a causal link between BSE and nv-CJD; however, there is no conclusive scientific proof of this fact.<sup>31</sup>

Another problem for controlling the disease is the lack of a diagnostic test. The complexity of the science underlying this novel infectious agent compounds this problem. However, recently there have been indications that some diagnostic tests are being developed using spinal fluid<sup>32</sup> or tonsil samples.<sup>33</sup> Especially given the long preclinical incubation period, a diagnostic test would greatly help in controlling and preventing the spread of the disease.

On the basis of this inconclusive information, and in earlier years much less information than this, FDA was attempting to determine what regulation was necessary in order to prevent, and if necessary control, BSE within the United States. This problem was accentuated by the fact that many scientists dispute the results of the epidemiological studies. There have been claims that England has been monopolizing tissue

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<sup>27</sup>Ruminant animals are a suborder of mammals that chew their cud and have four stomachs. See MERRIAM WEBSTER'S COLLEGIATE DICTIONARY (Frederick C. Mish et al. Eds., 1997).

<sup>28</sup>See *Food Safety: Oversight of the Centers for Disease Control Monitoring of Foodborne Pathogens, Hearing Before the Subcomm. on Human Resources and Intergovernmental Relations of the Comm. on Gov't Reform and Oversight*, 104<sup>th</sup> Cong. 79-80 (1996) (statement of Michael A. Friedman, M.D., FDA).

<sup>29</sup>See *Id.* at 81; *1996 Hearing 1*, *supra* note 5, at 159 (statement of Frederick A. Murphy, Univ. of Cal., Davis).

<sup>30</sup>See *1996 Hearing 1*, *supra* note 5, at 147 (statement of Robert Hahn, Public Voice for Food and Health Policy).

<sup>31</sup>See *1997 Hearing*, *supra* note 3, at 61-62 (statement of Lawrence B. Schonberger, M.D., CDC); *Mad Cows and Englishmen: the BSE scare*, 338 *ECONOMIST*, Mar. 30, 1996, at 25.

<sup>32</sup>See *1997 Hearing*, *supra* note 3, at 99 (statement of Clarence J. Gibbs, Ph.D., NIH).

<sup>33</sup>See A.F. Hill et al., *Investigation of Variant Creutzfeldt-Jakob Disease and Other Human Prion Diseases With Tonsil Biopsy Samples*, 353 *THE LANCET* 183 (1999).

samples,<sup>34</sup> that the research has been incompetent,<sup>35</sup> that the methods of obtaining data are inadequate,<sup>36</sup> and that there is a large amount of error in the clinical diagnosis of CJD.<sup>37</sup> This was the background against which FDA and other governmental agencies formulated their plan.

### III. History of BSE-Related Regulation in the United States

#### A.

In addition to FDA, there are other agencies that are working to prevent the occurrence and spread of BSE in the United States. While this paper will concentrate on FDA, the actions of that agency cannot be understood without knowing some of the contributions that these other agencies were making to the effort. In 1989, the United States Department of Agriculture (USDA) prohibited the importation of British cattle.<sup>38</sup> There were 499 cattle in the U.S. at that time that had been imported from Britain, and USDA quarantined these animals.<sup>39</sup> In 1990, USDA began surveillance measures for BSE that included examining the brains of numerous cows that were suspected of having or showed signs indicating that they could have BSE.<sup>40</sup> USDA also ordered an import alert in 1998 that extended the restriction on the importation of ruminants, their meat and byproducts not only to countries where BSE is known to exist but also to countries which do not have import requirements or surveillance measures that are as strict as those in the U.S. and, therefore,

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<sup>34</sup>See *The Other BSE Scandal*, ECONOMIST, Feb. 22, 1997, at 61.

<sup>35</sup>See *id.*

<sup>36</sup>See *1997 Hearing*, *supra* note 3, at 118 (statement of Frank Owen Bastion, M.D., Univ. of South Ala.).

<sup>37</sup>See *id.*

<sup>38</sup>See Richard Rhodes, *Deadly Feasts* 223 (1997). Given the lack of knowledge about the infectious agent and the fact that many of the products being imported would be given to the same species, USDA decided to follow a no risk approach, even though there was no evidence at the time implicating certain products. *Public Meeting 2*, *supra* note 2, at 31

<sup>39</sup>See Richard Rhodes, *Deadly Feasts* 223 (1997). After the announcement of the possible link between BSE, and nv-CJD, these 116 of these that were still alive at the time were killed. See *id.*

<sup>40</sup>See *id.*



could present a risk to this country.<sup>41</sup>

The Animal and Plant Health Inspection Service (APHIS), part of USDA, also has restrictions on imports and conducts surveillance for signs of BSE in the U.S.<sup>42</sup> In addition, APHIS has prepared an emergency response plan that would be implemented if BSE were found to exist in the U.S. and has procedures for educating the public about the risks posed by BSE.<sup>43</sup> APHIS also has a voluntary stock certification program for sheep in order to encourage the eradication of scrapie from the United States.<sup>44</sup>

The Centers for Disease Control and Prevention (CDC) gathers and interprets information from surveillance programs for CJD.<sup>45</sup> The CDC is also trying to increase the sensitivity of the surveillance for nv-CJD by starting a process of performing follow-up reviews for all patients under the age of 55 who are diagnosed with CJD and by trying to increase the number of cases that are officially reported.<sup>46</sup>

There is some concern that having multiple agencies working on this problem will lead to duplication, but those involved seem to feel that this is not a concern and that the effort is collaborative.<sup>47</sup> In April of 1996, there was an interagency meeting between the CDC, National Institutes of Health (NIH), FDA, USDA, and Department of Defense in order to distribute information about the conclusions reached at one of the World Health Organization (WHO) meetings on the subject and to coordinate the efforts of the different agencies.<sup>48</sup>

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<sup>41</sup>See USDA, Import Alert, IA #17-04, *Detention Without Physical Examination of Bulk Shipments of High-Risk Bovine Tissue from BSE Countries*, Sept. 25, 1998.

<sup>42</sup>See Specified Offal from Adult Sheep and Goats Prohibited in Ruminant Feed, 59 Fed. Reg. 44584, 44586 (1994) (proposed Aug. 29, 1994). APHIS sent U.S. pathologists to the United Kingdom in order to teach them about BSE. *1997 Hearing, supra* note 3, at 44 (statement of Dr. Linda A. Detwiler, APHIS).

<sup>43</sup>See *1997 Hearing, supra* note 3, at 42 (statement of Dr. Linda A. Detwiler, APHIS).

<sup>44</sup>See Specified Offal from Adult Sheep and Goats Prohibited in Ruminant Feed, 59 Fed. Reg. at 44586.

<sup>45</sup>See *1997 Hearing, supra* note 3, at 52-53 (statement of Lawrence B. Schonberger, M.D., CDC).

<sup>46</sup>See *id.* at 59.

<sup>47</sup>See *id.* at 90.

<sup>48</sup>See Animal Proteins Prohibited in Ruminant Feed; Proposed Rule, 62 Fed. Reg. 551, 564 (1997) (to be codified at 21 C.F.R. pt. 589.2000) (proposed Jan. 3, 1997).

## B.

The history of FDA's regulation in this area dates back to the 1980s because FDA became concerned about the issue as soon as BSE was identified in 1986.<sup>49</sup> The strategy of the food safety program promulgated by FDA is inspectional, which makes it a reactive, instead of preventive, system in most instances.<sup>50</sup> In the case of BSE, FDA's final strategy was to strengthen the voluntary industry ban on ruminant to ruminant feeding by classifying ruminant protein added to ruminant food as not generally recognized as safe (not GRAS) and, therefore, subject to control by FDA.<sup>51</sup> However, this final strategy, which actually was changed in the final rule to classify all mammalian protein in ruminant food as not GRAS, was the culmination of a history of FDA involvement in this area that dates back to the first identification of BSE.

Since the link between BSE and ruminant to ruminant feeding was first suggested in 1988, FDA was a participant in discussions, both nationally and internationally, attempting to understand the infectious agent and the BSE epidemic.<sup>52</sup> In 1989, when USDA's import restrictions were implemented, the National Renderers Association (NRA) and the Animal Protein Producers Industry (APPI) recommended that its members institute a voluntary ban on rendering adult sheep or providing such rendered material for cattle feed in order to eliminate the possible link between the disease scrapie in sheep and BSE.<sup>53</sup> In 1990, FDA increased the stringency of its new drug application review process for human drug products that are derived from bovine materials by requiring that the manufacturer document information about the source of the material and slaughter of the animal in order to insure that the risk is minimal.<sup>54</sup>

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<sup>49</sup> See *1996 Hearing 1*, *supra* note 5, at 95-96 (statement of Dr. Stephen Sundlof, CVM).

<sup>50</sup> See *id.* at 40-41 (statement of Michael A. Friedman, M.D., FDA).

<sup>51</sup> See *id.* at 10.

<sup>52</sup> See *id.* at 56-57.

<sup>53</sup> See Animal Proteins Prohibited in Ruminant Feed; Proposed Rule, 62 Fed. Reg. at 564; *1996 Hearing 1*, *supra* note 5, at 137-38 (statement of Don Franco, NRA).

<sup>54</sup> See FDA, *BSE Fact Sheet: Bovine Spongiform Encephalopathy and Creutzfeldt-Jakob Disease*, Jan. 2, 1997, 3, (last modified Jan. 26, 1999) <<http://www.fda.gov/cvm/fda/infores/updates/bse/bsefact.html>>.

FDA also began writing letters to different segments of the industry suggesting that they take measures to insure that any bovine products that they use are at a minimal risk of containing the BSE prion. These letters represented FDA's maximum authority under the law in this area.<sup>55</sup>

FDA sent the first letter on November 9, 1992, to the manufacturers of dietary supplements as the result of an inconclusive investigation of a CJD victim who had taken a dietary supplement that contained bovine materials.<sup>56</sup> The letter requests that the manufacturers investigate the sources of any bovine or ovine materials that they use in their products to determine if they are produced in countries with BSE or from flocks of sheep that have scrapie.<sup>57</sup> The letter also recommended reformulating products to use ingredients that are free of such contamination, requested gathering such information within two months, and suggested developing plans (that would be communicated to FDA) to assure that their products are not supplied by countries that have BSE.<sup>58</sup> FDA sent a letter on December 17, 1993, to the manufacturers of drugs, biological drugs, medical devices, and biological device products requesting that bovine materials not be used in the manufacture of products that are intended for use by humans and regulated by FDA if these materials originated in countries that have BSE.<sup>59</sup> USDA maintains a list of such countries.<sup>60</sup> FDA also sent two letters on August 17, 1994. One letter was to the manufacturers of FDA-regulated products for animals; it stated that they should not use materials derived from cattle that originated from or resided in a country containing BSE for manufacturing products regulated by FDA that were intended for use in the drugs or feed of animals.<sup>61</sup> The other was a second letter to the manufacturers and importers of dietary supplements reiterating and extending FDA's earlier warning that bovine tissues, and extracts derived from such tissues,

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<sup>55</sup>See FDA, *Public Forum on the Proposed Rule 21 CFR 589: Substances Prohibited from use in Animal Food or Feed*, Feb. 4, 1997, 9 [hereinafter *Public Meeting 1*].

<sup>56</sup>See Agency Letters to Manufacturers of FDA-Regulated Products, 59 Fed. Reg. 44591, 44591-92 (1994) (notice of Aug. 29, 1994).

<sup>57</sup>See *id.*

<sup>58</sup>See *id.*

<sup>59</sup>See *id.* at 44592.

<sup>60</sup>See *id.* at 44591.

<sup>61</sup>See *id.* at 44593.

should not come from cattle that have been in countries where BSE occurs.<sup>62</sup> This letter extended these recommendations to manufacturers of cosmetic products as well.<sup>63</sup> These letters also provided recommendations for the implementation of these requests.

FDA conducted a survey of the rendering practices used for sheep in 1992 and found that the industry was not fully implementing the voluntary ban and that ovine materials were still making their way into cattle and other animal feed.<sup>64</sup> As a result, on August 29, 1994, FDA issued a proposed rule that would declare that specified offal from adult sheep and goats is not GRAS for use in ruminant food and, therefore, would be an unapproved food additive.<sup>65</sup> This proposed rule was based on studies indicating the connection between feeding calves food containing material derived from sheep infected with scrapie and BSE, and it was aimed at preventing an outbreak of BSE in the U.S.<sup>66</sup> FDA did consider banning the use of ruminant tissue in ruminant feed; however, they decided that such a ban was not warranted at this time and that they would reconsider this decision if surveillance measures indicated the presence of BSE in the United States.<sup>67</sup> The industry contested this rule,<sup>68</sup> and FDA never progressed toward implementing it.<sup>69</sup> FDA evaluated all of the comments and later considered this option again when initiating an advance notice of proposed rulemaking (ANPRM) in 1996 — after the United Kingdom announced the possible link between BSE and nv-CJD.<sup>70</sup> In 1996, the industry also announced a voluntary ban on ruminant to ruminant feeding; however, there was no survey to determine how well the industry implemented this ban.<sup>71</sup> FDA also sent a letter on May 9,

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<sup>62</sup>See *id.* at 44593-94.

<sup>63</sup>See *id.* FDA did not extend this restriction to materials derived from sheep. See *id.*

<sup>64</sup>See *Animal Proteins Prohibited in Ruminant Feed* (Final Rule), 62 Fed. Reg. 30936, 30939 (1997) (codified at 21 C.F.R. 589); Richard Rhodes, *Deadly Feasts* 223 (1997).

<sup>65</sup>See *Update on BSE*, 11 FDA VETERINARIAN 5, (July/Aug. 1996) <<http://www.fda.gov/cvm/fda/infores/fdavaxet/1996/796fdavaxet.html>>; *Specified Offal from Adult Sheep and Goats Prohibited in Ruminant Feed*, 59 Fed. Reg. 44584, 44584 (1994) (proposed Aug. 29, 1994).

<sup>66</sup>See *id.*

<sup>67</sup>See *id.* at 44588.

<sup>68</sup>See Richard Rhodes, *Deadly Feasts* 223 (1997).

<sup>69</sup>See *SHELDON RAMPTON & JOHN STAUBER, MAD COW U.S.A.* 159-163 (1997).

<sup>70</sup>See *Protein Derived from Ruminants Prohibited in Ruminant Feed*, 61 Fed. Reg. 24253, 24253 (1996) (to be codified at 21 C.F.R. pt. 589) (advance notice of proposed rulemaking May 14, 1996); Richard Rhodes, *Deadly Feasts* 223-24 (1997).

<sup>71</sup>See *Animal Proteins Prohibited in Ruminant Feed*, 62 Fed. Reg. 551, 564 (1997) (to be codified at 21 C.F.R. pt. 589.2000) (proposed Jan. 3, 1997).

1996, to the manufacturers of products regulated by FDA in order to restate their concerns about BSE and recommend that the manufacturers take measures to assure themselves that any bovine products that they use are not from cattle that were born, killed, or raised in a country known to have BSE.<sup>72</sup> Additionally, FDA and USDA hosted a symposium on the issue of TSE's in order to facilitate discussion of the issue.<sup>73</sup> FDA also formed an intra-agency working group as well as a CJD Advisory Committee, which was formed in 1995 and rechartered in 1996 as the TSE Advisory Committee.<sup>74</sup> Recently, FDA has proposed requiring that the manufacturers of certain products that contain cellular and tissue-based material register with FDA, listing the ingredients of such products, and that human dura mater be regulated as well.<sup>75</sup> These actions all lead up to FDA's final rule and the question of whether such action was sufficient to protect the American public.

### C.

On May 14, 1996, FDA issued an ANPRM to solicit comments about the possibility of banning protein derived from ruminants being used in ruminant feed.<sup>76</sup> The ANPRM was made only two months after the United Kingdom announced the possible link between BSE and nv-CJD. This notice was issued against the background of a WHO meeting in April that concluded that there was circumstantial evidence suggesting a link between these two diseases and recommending that all countries ban the use of ruminant material in ruminant feed.<sup>77</sup>

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<sup>72</sup> See *Update on BSE*, 11 FDA VETERINARIAN 5, (July/Aug. 1996) <<http://www.fda.gov/cvm/fda/infores/fdavet/1996/796fdavet.html>>.

<sup>73</sup> See *id.*

<sup>74</sup> See 1997 Hearing, *supra* note 3, at 17 (statement of Michael A. Friedman, M.D., FDA).

<sup>75</sup> See Establishment Registration and Listing for Manufacturers of Human Cellular and Tissue-Based Products, 62 Fed. Reg. 26744, (1998) (to be codified at 21 C.F.R. pts. 207, 807, 1271) (proposed May 14, 1998).

<sup>76</sup> See Protein Derived from Ruminants Prohibited in Ruminant Feed, 61 Fed. Reg. 24253 (1996) (to be codified at 21 C.F.R. pt. 589) (advance notice of proposed rulemaking May 14, 1996).

<sup>77</sup> See Protein Derived From Ruminants Prohibited in Ruminant Feed, 61 Fed. Reg. 24253, 24253-54 (advance notice of

On January 3, 1997, FDA issued the proposed rule, which generally declares that ruminant and mink protein is not GRAS when added to food for ruminant animals, requires cautionary labeling on such products, and mandates the maintenance of records in order for FDA to assess compliance.<sup>78</sup> The proposed ban was stronger than the previously proposed rule from 1994, which FDA did not act upon because of opposition from the industry and the lack of sufficient inspectors to enforce the rule.<sup>79</sup> FDA designed this rule in order to decrease the risk of an adverse effect on an individual or population if an epidemic of BSE were to occur in the United States and results show that there is a relationship between BSE and nv-CJD.<sup>80</sup> The proposed rule would have prevented using ruminant tissue as a food additive until there is scientific data proving to FDA that it is safe.<sup>81</sup> The proposed rule also suggested several alternatives for consideration.<sup>82</sup> Reactions to this rule varied. FDA held two open forums for discussion of the rule, and reactions ranged from feeling that the agency was going too far to feeling that it was not doing enough.<sup>83</sup> However, in order to make the safest decision, even if it is later shown to be excessive, the rule needed to be imposed at that time.<sup>84</sup>

On April 17, 1997, FDA announced the availability of a draft rule, which changed the ban to exclude all mammalian tissues from ruminant feed and allowed for a period of comment on the draft.<sup>85</sup> The final rule was published on June 5, 1997 and generally went into effect on August 4, 1997.<sup>86</sup> The final rule declared that “protein derived from mammalian tissues for use in ruminant feed is a food additive.... The use or intended use in ruminant feed of any material that contains protein derived from mammalian tissues causes the feed to

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proposed rulemaking May 14, 1996). The WHO also had made this suggestion earlier, though. *See* discussion *infra* Part V.C.

<sup>78</sup>*See* Animal Proteins Prohibited in Ruminant Feed; Proposed Rule, 62 Fed. Reg. 551, 570 (1997) (to be codified at 21 C.F.R. pt. 589.2000) (proposed Jan. 3, 1997).

<sup>79</sup>*See* Lawrence K. Altman, *Cow Disease Sparks Voluntary Rules on Feed*, N.Y. Times, Mar. 30, 1996, §1, at 10.

<sup>80</sup>*See* Animal Proteins Prohibited in Ruminant Feed; Proposed Rule, 62 Fed. Reg. at 561.

<sup>81</sup>*See* 1997 Hearing, *supra* note 3, at 12-13 (statement of Michael A. Friedman, M.D., FDA).

<sup>82</sup>*See* Animal Proteins Prohibited in Ruminant Feed; Proposed Rule, 62 Fed. Reg. 551, (1997) (to be codified at 21 C.F.R. pt. 589.2000) (proposed Jan. 3, 1997).

<sup>83</sup>*See* Public Meeting 2, *supra* note 2; Public Meeting 1, *supra* note 55.

<sup>84</sup>*See* 1996 Hearing 1, *supra* note 5, at 123 (statement of Dr. Frederick A. Murphy, Univ. of Cal., Davis).

<sup>85</sup>*See* Animal Proteins in Ruminant Feed; Draft Rule; Availability, 62 Fed. Reg. 18728, 18728 (1997) (draft available Apr. 17, 1997).

<sup>86</sup>*See* Animal Proteins Prohibited in Ruminant Feed (Final Rule), 62 Fed. Reg. 30936 (1997) (codified at 21 C.F.R. 589).

be adulterated and in violation of the act...”<sup>87</sup> Mammalian tissues are limited by the rule to proteinaceous material, but the rule excludes blood, gelatin, cooked foods that have previously been offered as human food and have subsequently been further heat processed, milk, and mammalian protein derived solely from pigs or horses.<sup>88</sup> Although specific requirements and exemptions are described in the rule, it also generally institutes labeling requirements and recordkeeping requirements of one year.<sup>89</sup> Although some comments suggest that this rule institutes more stringent requirements than the scientific evidence may suggest, it is more practical and enforceable, which increases the chance that the industry will comply with the rule.<sup>90</sup> The final rule acknowledges that recognition of GRAS status cannot be based on the absence of evidence that a substance is dangerous and puts the burden of proving safety on the industry, because FDA does not think that this matter can be delayed while scientists conduct further research.<sup>91</sup> “FDA believes that the rule selected is the most cost-effective regulatory alternative that meets the objective of the agency.”<sup>92</sup> Thus, 11 years after the first recognition of BSE, FDA had completed a regulation to prevent the spread of the disease in the United States. The question inevitably arises whether FDA did too much, did enough, and did it quickly enough.

#### IV. Problems with Action

##### A.

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<sup>87</sup>Animal Proteins Prohibited in Ruminant Feed, 21 C.F.R. 589.2000(b); Animal Proteins Prohibited in Ruminant Feed (Final Rule), 62 Fed. Reg. at 30977.

<sup>88</sup>*See id.* at 30976-77.

<sup>89</sup>*See id.* at 30976-78.

<sup>90</sup>*See id.* at 30943.

<sup>91</sup>*See id.* at 30948-49.

<sup>92</sup>*Id.* at 30974.

There were a number of people who thought that FDA should not impose a ban on feeding ruminant protein to ruminant animals. One of the foremost reasons for this assertion was the idea that such decisions should be based on science.<sup>93</sup> At a Congressional Hearing in 1996, Dr. Franco, a member of the NRA, asked that we err on the side of science and not on the side of safety because the risk factors in the U.S. are not the same as those in the United Kingdom.<sup>94</sup> He said that the industry was in favor of evaluating regulatory options on the basis of science instead of public opinion or politics, and that the ban is unnecessary if there is no evidence that BSE exists in U.S. cattle.<sup>95</sup>

FDA explicitly considered a no action alternative and found that such an option was supported merely by the lack of evidence documenting an immediate threat to the public health and by other data suggesting that any risk was minimal.<sup>96</sup> Evidence suggesting that there is no direct threat included the continually reiterated fact that there are no cases of BSE in the United States, that evidence cannot conclusively prove that the perpetuation of the disease results from the spread of the infectious agent through animal feed, that there is no direct proof of the link between BSE and nv-CJD, and that the WHO has stated that other countries are not at as great a risk as the United Kingdom.<sup>97</sup> Others also commented that designating such protein as not GRAS would stigmatize the products in a way that the available scientific information did not warrant.<sup>98</sup> FDA had to balance these issues, which mainly relate to the uncertainty of the science, against the demands of those who felt that action was necessary.

There were numerous other voices arguing that action was imperative. At a Congressional hearing in 1996, Representative Shays said in his opening speech that “Rather than provide a pretext for inaction, the lack of hard proof should compel government and industry to aggressive safety measures that meet every probable,

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<sup>93</sup>See *Public Meeting 2*, *supra* note 2, at 37.

<sup>94</sup>See *1996 Hearing 1*, *supra* note 5, at 154-55 (Don Franco, NRA).

<sup>95</sup>See *id.* at 133.

<sup>96</sup>See Animal Proteins Prohibited in Ruminant Feed, 62 Fed. Reg. 551, 553 (1997) (to be codified at 21 C.F.R. pt. 589.2000) (proposed Jan. 3, 1997).

<sup>97</sup>See Animal Proteins Prohibited in Ruminant Feed, 62 Fed. Reg. 551, 553-54 (1997) (to be codified at 21 C.F.R. pt. 589.2000) (proposed Jan. 3, 1997).

<sup>98</sup>See *Public Meeting 2*, *supra* note 2, at 39.



possible, or even theoretical threat.”<sup>99</sup> The experiences that our country has had with Hepatitis and AIDS suggest that new infectious agents can avoid detection by our defenses unless we are extremely alert to the possibilities, theoretical and actual, that it will occur in the United States.<sup>100</sup> Even a member of the National Cattlemen’s and Beef Association has said that we cannot be wrong, which is the reason that we are taking such an incredible preventative step.<sup>101</sup> Proponents of action point to the fact that the rendering techniques in the United States may not totally eliminate the infectious agent, so given that scrapie and other TSE’s occur in this country, the possibility does exist that BSE could spread here if we do not have restrictions on animal feeding practices.<sup>102</sup> FDA stated that the cost in human and animal lives (as well as economic costs) that could result if a BSE epidemic occurred in the United States warrants taking the actions proposed by the rule.<sup>103</sup> The CDC, USDA, and WHO all recommended or supported a ruminant to ruminant feeding ban, and such a ban would greatly help to alleviate public concern.<sup>104</sup> Other reasons for action included the fact that our border is not completely sealed and that the risk of amplifying BSE could be greater in the United States.<sup>105</sup> Some proponents of action even requested an interim or temporary ban while the final rule was being prepared.<sup>106</sup>

This decision came down to balancing the uncertainties of science against theoretical risks. It has been suggested that risk assessment and risk management should be performed by different groups in order to prevent biasing the risk assessment by ideas about what action one thinks is necessary.<sup>107</sup> In this case, it seems that although the scientific determinations were not conclusive, there was enough suggestive evidence

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<sup>99</sup> 1996 Hearing 1, *supra* note 5, at 2 (statement of Rep. Christopher Shays, chairman of subcommittee).

<sup>100</sup> See 1997 Hearing, *supra* note 3, at 2 (statement of Rep. Christopher Shays, chairman of subcommittee).

<sup>101</sup> See Lawrence K. Altman, *Cow Disease Sparks Voluntary Rules on Feed*, N.Y. Times, Mar. 30, 1996, §1, at 10.

<sup>102</sup> See 1997 Hearing, *supra* note 3, at 24 (statement of Michael A. Friedman, M.D., FDA).

<sup>103</sup> See Animal Proteins Prohibited in Ruminant Feed, 62 Fed. Reg. 551, 554 (1997) (to be codified at 21 C.F.R. pt. 589.2000) (proposed Jan. 3, 1997).

<sup>104</sup> See *id.*

<sup>105</sup> See 1996 Hearing 1, *supra* note 5, at 143 (Statement of Robert Hahn, Public Voice for Food and Health Policy).

<sup>106</sup> See *id.*

<sup>107</sup> See COMMITTEE TO STUDY HIV TRANSMISSION THROUGH BLOOD AND BLOOD PRODUCTS, INSTITUTE OF MEDICINE, HIV ANT THE BLOOD SUPPLY (Lauren B. Leveton, Harold C. Sox, Jr., & Michael A. Stoto eds.) 210 (1995).

to warrant action on the part of FDA. The risks of inaction were too large. Although assessments of the situation ranged from complete faith in the current system to apocalyptic predictions, even the circumstantial evidence alone could not be ignored. Action was necessary.

## B.

Although there are the inevitable criticisms that FDA did not work quickly enough, a number of those involved asked for more time to consider the rule and the alternative proposals. FDA declined to allow additional time for comment on the final rule.<sup>108</sup> Members of the NRA and the APPI wrote to FDA asking them to extend the comment period by 90 days.<sup>109</sup> Their reasons included the complexity and number of issues involved, the fact that FDA requested detailed opinions on six different alternative proposals which could not be responded to in the time provided, the fact that the lengthy, substantive documents require time to analyze, and the time necessary to provide meaningful comments.<sup>110</sup> Some appealed to the idea of cooperating to create a rule that would meet everyone's goals by allowing more time for comment.<sup>111</sup> Others suggested that FDA issue a compliance policy guideline which would allow more time for resolving some of the questions that are involved before they issued a rule.<sup>112</sup> Other options included an interim rule; however, this is an exception to the Administrative Procedure Act that is only allowed if the procedures are impracticable, against the public interest, or not necessary.<sup>113</sup> Despite all of these requests to slow the

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<sup>108</sup>See *Animal Proteins Prohibited in Ruminant Feed (Final Rule)*, 62 Fed. Reg. 30936, 30962 (1997) (codified at 21 C.F.R. 589).

<sup>109</sup>See *Public Meeting 1*, *supra* note 55, at 70.

<sup>110</sup>See *Public Meeting 1*, *supra* note 55, at 70-71; *Public Meeting 2*, *supra* note 2, at 44.

<sup>111</sup>See *Public Meeting 2*, *supra* note 2, at 35.

<sup>112</sup>See *Public Meeting 1*, *supra* note 55, at 66.

<sup>113</sup>See *Animal Proteins Prohibited in Ruminant Feed (Final Rule)*, 62 Fed. Reg. 30936, 30950 (1997) (codified at 21 C.F.R. 589).

process down and allow time for more discussion, there were a number of people complaining about the length of time that it took to promulgate a rule on the issue.

One member of FDA admitted before a Congressional committee that FDA could have acted sooner. When being asked why FDA did not take action a year ago, Dr. Friedman was forced to admit that there was no practical reason why they could not have done so.<sup>114</sup> He also had to explain that the reason that they started acting in 1996, when the WHO had made such a recommendation in 1991, was their analysis indicating that the factors affecting the risk in the United States were different from those present in the United Kingdom.<sup>115</sup> The Congressional Hearing also required that FDA explain why it was not taking emergency rulemaking procedures or invoking a temporary ban.<sup>116</sup> Despite reassurance that FDA would “expedite regulations,”<sup>117</sup> there are many who felt that the pace was still too slow, that the issue was being discussed too much before implementation,<sup>118</sup> and that the government’s actions were “shamefully inadequate” when the period during which prevention was possible may have been elapsing.<sup>119</sup> FDA stated that it made the draft rule available, thus lengthening the amount of time before the final rule was implemented, because of the complexity of the issues involved.<sup>120</sup> However, the agency did decline to extend the effective date for the statute, although it allowed an extra sixty days to use up current supplies.<sup>121</sup> Thus, the numerous perspectives on this issue make it difficult to assess whether FDA was adequately performing its job of protecting the American food supply. In order to make a more thorough assessment of this question, it is necessary to compare FDA’s actions against some of the available standards.

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<sup>114</sup>See *1996 Hearing 1*, *supra* note 5, at 99 (statement of Michael A. Friedman, M.D., FDA).

<sup>115</sup>See *id.* at 99-100.

<sup>116</sup>See *id.* at 144, 153.

<sup>117</sup>See Lawrence K. Altman, *Cow Disease Sparks Voluntary Rules on Feed*, N.Y. Times, Mar. 30, 1996, §1, at 10.

<sup>118</sup>See SHELDON RAMPTON & JOHN STAUBER, *MAD COW U.S.A.* 211 (1997).

<sup>119</sup>See Press Release, International Center for Technology Assessment (Jan. 7, 1999) <<http://www.icta.org/ctanews/madcow.htm>>.

<sup>120</sup>See Animal Proteins in Ruminant Feed; Draft Rule; Availability, 62 Fed. Reg. 18728, 18728 (1997) (draft available Apr. 17, 1997).

<sup>121</sup>See Animal Proteins Prohibited in Ruminant Feed (Final Rule), 62 Fed. Reg. 30936, 30960 (1997) (codified at 21 C.F.R. 589).

## V. Enough and Fast Enough?

### A.

In a 1997 Congressional Hearing, it was suggested that the recommendations and comments made in the 1995 report of the IOM pertaining to HIV could serve as a framework for evaluating FDA's actions concerning the possibility of transmitting CJD through the blood supply.<sup>122</sup> This report suggested that FDA had missed opportunities for action by choosing the least aggressive alternatives, often due to uncertainty about the science, and that a more systematic approach should be used in similar situations.<sup>123</sup> In his statement for a Congressional Hearing, Dr. Friedman said that FDA had learned from its experience with HIV and responded to the threat that these types of infectious agents pose to the blood supply in the United States.<sup>124</sup> FDA is the main regulatory agency that is responsible for blood and blood products in this country and generally bases decisions relating to the blood supply on scientific consensus.<sup>125</sup> The inability of the system to deal with a problem which is surrounded by uncertainties of science was evidenced by the result of the episode with HIV.<sup>126</sup> The 1995 report lists CJD as one of the other possible infectious agents that could pose a threat to the blood supply.<sup>127</sup> The report made six recommendations that applied to FDA. I will consider whether FDA has implemented each of three of these suggestions.<sup>128</sup>

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<sup>122</sup>See 1997 Hearing, *supra* note 3, at 38 (statement of Michael A. Friedman, M.D., FDA).

<sup>123</sup>See *id.*

<sup>124</sup>See *id.* at 39.

<sup>125</sup>See COMMITTEE TO STUDY HIV TRANSMISSION THROUGH BLOOD AND BLOOD PRODUCTS, INSTITUTE OF MEDICINE, HIV AND THE BLOOD SUPPLY (Lauren B. Leveton, Harold C. Sox, Jr., & Michael A. Stoto eds.) 7 (1995).

<sup>126</sup>See *id.* at 2.

<sup>127</sup>See *id.* at 130.

<sup>128</sup>The recommendations that pertained to FDA were numbers 6 through 11. The last three recommendations relate to the system of advisory committees that FDA has to help it evaluate decisions. Recommendation #9 asked for balance in the composition of the committee advising FDA about blood products in order to make sure that there are both members who are involved in the industry and who are independent. Recommendation #10 suggested that FDA make its expectations clear to its advisory committees and also that it perform an independent review of these committees. Recommendation #11 stated that FDA needs reliable information about the blood supply and should be able to analyze the information and assess regulatory decisions on its own. See COMMITTEE TO STUDY HIV TRANSMISSION THROUGH BLOOD AND BLOOD PRODUCTS, INSTITUTE OF

There is no conclusive evidence that CJD can be transmitted through blood. However, it has been shown that injection of a certain component of blood from patients with CJD into rodents can transmit the disease.<sup>129</sup> The infectious agent can occasionally be found in blood at low titers, but epidemiological data suggest that if the infectious agent is present in the blood, the risk must be very low.<sup>130</sup> The WHO also considers these products to be safe.<sup>131</sup> However, any risk, even if minimal, obviously generates great concern because people with CJD can donate blood and not know that they have the disease.

Recommendation #6 suggested that when uncertainties prevent complete elimination of a risk, FDA should promote partial solutions, as long as they do not cause harm.<sup>132</sup> Examples of such actions could include destroying unscreened blood, phased recall of such blood, and “lookback” procedures to notify those who received infected blood.<sup>133</sup> FDA’s actions in this area actually predate these recommendations in some cases; however, FDA has recently attempted to institute partial solutions that seem aimed at eliminating some of the risk, if all risk cannot be eliminated. In 1987, an FDA letter recommended deferral of donors who had been the recipients of human pituitary-derived growth hormone; however, this recommendation did not institute “lookback” procedures for those who later developed CJD.<sup>134</sup> FDA has since suggested that blood products from donors who have a greater risk of developing CJD should be quarantined and destroyed.<sup>135</sup> In 1993, FDA instituted more complete reporting in order to identify safety concerns.<sup>136</sup> In 1994, blood product manufacturers quarantined derivatives of such identified blood, and in 1995, FDA instituted an interim pol-

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MEDICINE, HIV ANT THE BLOOD SUPPLY (Lauren B. Leveton, Harold C. Sox, Jr., & Michael A. Stoto eds.) 15 (1995). Because this paper is focusing on whether the actions that FDA took are sufficient, it will not assess possible areas, such as problems in advisory committees, that could have led to such wrong decisions.

<sup>129</sup> See 1997 Hearing, *supra* note 3, at 28 (statement of Michael A. Friedman, M.D., FDA).

<sup>130</sup> See 1997 Hearing, *supra* note 3, at 64 (statement of Lawrence B. Schonberger, M.D., CDC).

<sup>131</sup> See Animal Proteins Prohibited in Ruminant Feed, 62 Fed. Reg. 551, 561 (1997) (to be codified at 21 C.F.R. pt. 589.2000) (proposed Jan. 3, 1997).

<sup>132</sup> See COMMITTEE TO STUDY HIV TRANSMISSION THROUGH BLOOD AND BLOOD PRODUCTS, INSTITUTE OF MEDICINE, HIV ANT THE BLOOD SUPPLY (Lauren B. Leveton, Harold C. Sox, Jr., & Michael A. Stoto eds.) 14 (1995).

<sup>133</sup> See *id.* at 227.

<sup>134</sup> See Center for Biologics Evaluation and Research, Letter about *Revised Precautionary Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) by Blood and Blood Products*, Dec. 11, 1996, at 2.

<sup>135</sup> See 1997 Hearing, *supra* note 3, at 35 (statement of Michael Friedman, M.D., FDA).

<sup>136</sup> See *id.* at 30 (statement of Michael Friedman, M.D., FDA).

icy of withdrawing all blood products from donors who were later diagnosed with CJD.<sup>137</sup> To insure safety, there was a provision for release of this blood, with a special label, in the event of a documented shortage.<sup>138</sup> Another example of such partial solutions is that FDA made an exception for pools of plasma derivatives when one donor had only one known family member with CJD.<sup>139</sup> These were all partial solutions to try to respond to the fact that there is some, but inconclusive, evidence that blood can transmit CJD. Because there is no way of determining whether the blood contains the infectious agent, FDA instituted these other methods in order to reduce the risk.

Recommendation #7 acknowledged the fact that the amount of knowledge that we have is changing and suggested that FDA periodically review key decisions that it has made regarding the blood supply and evaluate them in the light of new information.<sup>140</sup> It appears that in this area, especially recently, FDA is making an effort to revise its policies. At the end of 1996, FDA revised its policy to stress the importance of both deferring donors who are at increased risk and investigating the family history of CJD in donors.<sup>141</sup> More recently, in 1999, a scientific advisory panel suggested that FDA consider barring blood donations from those people who have visited Great Britain since 1980, and FDA's advisory committee decided to consider this issue.<sup>142</sup> These decisions all show an effort to reevaluate previous decisions in the light of new information. These recommendations can also be applied to other areas of FDA regulation. In the realm of protecting the animal and public health from BSE, there were options that FDA could have considered which would have been partial solutions during the period of debate about whether to institute a full ruminant to ruminant or mammalian to ruminant feeding ban. One of those options could have been to act on the 1994 proposed rule regarding specified offal from sheep and goats. Such a ban could have been a partial solution in the light

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<sup>137</sup>See *id.* at 31-32 (statement of Michael Friedman, M.D., FDA).

<sup>138</sup>See *id.*

<sup>139</sup>See Center for Biologics Evaluation and Research, Letter about *Revised Precautionary Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) by Blood and Blood Products*, Dec. 11, 1996, at 8.

<sup>140</sup>See COMMITTEE TO STUDY HIV TRANSMISSION THROUGH BLOOD AND BLOOD PRODUCTS, INSTITUTE OF MEDICINE, HIV ANT THE BLOOD SUPPLY (Lauren B. Leveton, Harold C. Sox, Jr., & Michael A. Stoto eds.) 14 (1995).

<sup>141</sup>See *1997 Hearing*, *supra* note 3, at 13 (statement of Michael Friedman, M.D., FDA).

<sup>142</sup>See Warren Leary, *Keeping 'Mad Cow' Away from U.S. Blood Supply*, N.Y. TIMES, Jan. 19, 1999, at D1.

of the theories about BSE that existed at the time. This decision could then have been later reevaluated in the light of new knowledge about the transmission of BSE, and the full mammalian to ruminant ban could then have been implemented. Thus, although FDA seems to have implemented these two recommendations to a significant degree in their handling of the blood supply, they did not carry these lessons over into other areas of regulation.<sup>143</sup>

Recommendation #8 pleaded for clarity in requests to regulated organizations both as pertaining to the requirements desired and whether compliance is mandatory.<sup>144</sup> FDA seems to have achieved this by stating in its letters that plans for compliance should be submitted to FDA within a certain period of time.<sup>145</sup> The organizations are sometimes also required to submit the dates on which such changes were established and implemented.<sup>146</sup> However, in its final rule relating to animal feed, FDA did not specify specific procedures for cleaning out the machinery. This fact has put a great burden on each feed mill operator to develop a process that is sufficient and then to prove this fact to the inspector.<sup>147</sup> So once again, FDA has not necessarily carried these lessons from dealing with the blood supply over to other areas of regulation.

FDA seems to have attempted to implement these recommendations, especially in the regulation of the blood supply. One area in which FDA has also excelled is in implementing education programs to promote compliance with the rule.<sup>148</sup> The IOM report emphasized the importance of risk communication.<sup>149</sup> FDA has tried to increase the public availability of information regarding recalls and withdrawals and has tried

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<sup>143</sup>FDA has revised decisions in light of new scientific information in areas other than blood products, though. One example of this is gelatin. See discussion *infra* Part V.D.2.

<sup>144</sup>See COMMITTEE TO STUDY HIV TRANSMISSION THROUGH BLOOD AND BLOOD PRODUCTS, INSTITUTE OF MEDICINE, HIV ANT THE BLOOD SUPPLY (Lauren B. Leveton, Harold C. Sox, Jr., & Michael A. Stoto eds.) 14-15 (1995).

<sup>145</sup>See Center for Biologics Evaluation and Research, Letter about *Revised Precautionary Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) by Blood and Blood Products*, Dec. 11, 1996, at 9.

<sup>146</sup>See *id.*

<sup>147</sup>See Jon F. Scheid, *Successful BSE Teleconference Held for Feed Industry*, 8 FDA Veterinarian 5 (Sept./Oct. 1998) <<http://www.fda.gov/cvm/fda/infores/fdavet/1998/SEPT1.htm>>.

<sup>148</sup>See CVM, FDA, *Enforcement Strategy Update: FDA Regulation 21 CFR 589.2000 The BSE Feed Regulation*, at 16-18 (December 1998) <<http://www.fda.gov/cvm/fda/TOCs/strat.PDF>> [hereinafter *Enforcement Strategy Update*].

<sup>149</sup>See COMMITTEE TO STUDY HIV TRANSMISSION THROUGH BLOOD AND BLOOD PRODUCTS, INSTITUTE OF MEDICINE, HIV ANT THE BLOOD SUPPLY (Lauren B. Leveton, Harold C. Sox, Jr., & Michael A. Stoto eds.) 211-12 (1995).

to increase the amount of input that the public has in this area.<sup>150</sup> Although not directly related to the blood supply, FDA has tried to educate those involved in the industry about the threat that BSE poses. As will be elaborated on in the next section, FDA is trying to discuss the problem and the solutions with those involved. Thus, FDA seems to have implemented these recommendations when dealing with the blood supply, but it has not necessarily carried these lessons over into its other areas of regulation.

## B.

Another method of gauging whether FDA took enough action is to analyze the enforcement strategy goals for the regulation and whether or not they have been achieved. This process will determine what the current situation is in order to assess whether the final rule is actually having its desired effect.

The main objective of the original enforcement strategy was to achieve 100% actual compliance, not just compliance with the recordkeeping requirements of the rule.<sup>151</sup> The agency set goals for inspection and education for the first two years, which aimed at inspecting all of the firms that were affected by the rule and a group of the producers.<sup>152</sup> The implementation of these goals also involved tracing shipments of animal feed backwards and forwards through the system of distribution in order to determine the degree of compliance of all involved in the process.<sup>153</sup> The inspections were aimed at educating the members of the industry, attaining compliance without resorting to enforcement actions, using enforcement actions when necessary, and gathering information in order to plan future strategies.<sup>154</sup> The educational strategy involved using both general and individual teaching to conduct education programs that reach a significant number

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<sup>150</sup> See *1997 Hearing*, *supra* note 3, at 40 (statement of Michael Friedman, M.D., FDA).

<sup>151</sup> See *Enforcement Strategy Update*, *supra* note 148, at 8.

<sup>152</sup> See *id.*

<sup>153</sup> See *id.* at 9.

<sup>154</sup> See *id.*



of those whom the rule affects and that are effective.<sup>155</sup> FDA has stated that inspections will be performed by FDA as well as state personnel and that they will follow through with enforcement actions if there are knowing, willful, or egregious violations of the rule.<sup>156</sup> However, FDA views the inspection as the first chance to educate the violator about a problem and obtain a promise to correct the violation.<sup>157</sup> Often a warning will be sent out; however, the agency is prepared to use its other remedial options (seizure, injunction and prosecution) if they are necessary.<sup>158</sup>

FDA's enforcement actions in the first year of implementation determined that overall compliance rates (percentage with no violations) ranged from 85% for renderers to 48% for unlicensed feed mills; however, compliance rates for each of the individual requirements were much higher.<sup>159</sup> Inspectors found no cases in which enforcement actions for egregious violations were necessary. Education about the rule is being promulgated through Small Entity Compliance Guides, the Center for Veterinary Medicine (CVM) home page, distribution of educational materials, and presentations at numerous meetings.<sup>160</sup> A pilot study showed that overall awareness of the regulation was at 96%.<sup>161</sup>

Enforcement of the rule can be difficult because BSE has not been found in the United States and there are neither tests to determine if the infectious agent is present before the animal shows clinical signs of the disease nor to determine the species of the material in the animal feed. As a result, enforcement generally depends on following the paper trail for the shipment.<sup>162</sup> In terms of assaying for BSE, we are the only country in the world that is consistently performing two methods of diagnosis on all cattle analyzed.<sup>163</sup>

In mid-1998, almost 1000 inspections had been performed, and the percentage of firms in compliance had

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<sup>155</sup>See *id.* at 9-10.

<sup>156</sup>See CVM, A Report on the Questions Asked and Answered on the Air During the June 24 BSE Satellite Teleconference 30, 17 <<http://www.fda.gov/cvm/fda/TOCs/bsetrans.html>>.

<sup>157</sup>See *id.* at 17.

<sup>158</sup>See *id.*

<sup>159</sup>See *Enforcement Strategy Update*, *supra* note 148, at 11-13.

<sup>160</sup>See *id.* at 17.

<sup>161</sup>See *id.*

<sup>162</sup>See *id.* at 3.

<sup>163</sup>See *Public Meeting 2*, *supra* note 2, at 19-20.

increased, as had awareness of the statute.<sup>164</sup> However, despite all of these encouraging statements and evidence of compliance, there are some areas of concern.

A pilot program in Nebraska indicated that although the rate of overall compliance was good, there were problems with the cautionary labeling requirements; however, the NRA addressed these problems in a letter that it sent to all rendering facilities.<sup>165</sup> Additional concerns that this pilot program raised included the fact that jobbers (who gather animal material for selling at a profit) do not use invoices, sell to anyone, and can be difficult to identify; there could be cross-contamination through the trucks that are used to ship the feed; some lack of inspection of renderers by USDA; and the need for standardized clean out procedures.<sup>166</sup>

Thus, the enforcement program appears to be achieving good results and addressing new problems as they arise. If this trend continues, hopefully they will be able to achieve their goal of 100% compliance. There does not seem to be a cause for concern that FDA is not doing its utmost to implement its regulation.

## C.

One way of gauging whether FDA acted quickly enough or should have taken more stringent measures at an earlier date is to compare FDA's actions with the recommendations of the WHO. The WHO has held seven meetings or consultations<sup>167</sup> on the topic of TSE's and made recommendations as to actions that countries should take.

The first WHO meeting on TSE's was held on November 12-14, 1991. At this time FDA's only actions

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<sup>164</sup>See CVM, A Report on the Questions Asked and Answered on the Air During the June 24 BSE Satellite Teleconference 16 <<http://www.fda.gov/cvm/fda/TOCs/bsetrans.html>>.

<sup>165</sup>See *Enforcement Strategy Update*, *supra* note 148, at attachment H 3

<sup>166</sup>See *id.* at attachment H 6.

<sup>167</sup>Information from the 1991 and 1993 meetings is taken from memorandums printed in the Bulletin of the World Health Organization. Information about the two 1996 meetings and the 1997 meeting is taken from the reports or excerpts of the report from those meetings that were available on the web. I was unable to obtain a copy or summary of the report from the 1995 meeting or the 1998 meeting.

had been an increase in the stringency of review of new drug applications that involved bovine materials. There were also the USDA importation prohibition and a voluntary ban by the sheep rendering industry that were in place at this time.<sup>168</sup> The WHO report suggested that the change in rendering practices was an important factor in the emergence of BSE and stated that the disease can be transmitted orally in experimental settings.<sup>169</sup> The report also discussed the fact that the species barrier is unpredictable and that exposure due to occupation and medical products should be considered.<sup>170</sup> The report did state that there is no evidence supporting the theory that scrapie causes CJD, but it acknowledged that because one cannot necessarily assume that the same applies to BSE, it is necessary to take steps to reduce risk and prevent transmission.<sup>171</sup> The WHO report listed categories of infectivity for different types of tissue in which brain and spinal cord ranked highest for infectivity.<sup>172</sup> The report said that studies suggest that contamination of feed is the cause of the disease and can amplify the problem by recycling cattle.<sup>173</sup> It recommended that countries without a current BSE presence should create surveillance programs to detect any cases if they should arise, and if risk factors, such as feeding ruminant protein to ruminant animals, scrapie, etc., are present, they should consider banning specified offals, which contain greater amounts of the infectious agent, from ruminant feed.<sup>174</sup> This recommendation was made three years before FDA even proposed banning specified offals from sheep — a proposal that was never acted upon — although there was a voluntary ban in place by sheep renderers and FDA considered conditions in the United States to be different from those in Great Britain.<sup>175</sup> The WHO report also said that to minimize risk to humans, specified offals should not be used in food for animals or humans and that muscle, milk, tallow, and some other specified tissues do

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<sup>168</sup> See discussion *infra* Part III.B.

<sup>169</sup> See *Public Health Issues Related to Animal and Human Spongiform Encephalopathies: Memorandum from a WHO Meeting*, 70 BULL. OF THE WORLD HEALTH ORG. 183, 184 (1992).

<sup>170</sup> See *id.* at 185.

<sup>171</sup> See *id.* at 185-86.

<sup>172</sup> See *id.* at 186.

<sup>173</sup> See *id.* at 187.

<sup>174</sup> See *id.*

<sup>175</sup> See discussion *supra* Part III.B.; 1996 Hearing 1, *supra* note 5, at 99-100.

not appear to pose a risk to health.<sup>176</sup> It also recommended carefully selecting the source of materials for ingredients in medical products and cosmetics, including the type of material, the conditions of collection, the amount of material, the method used to administer the material, and any procedures used to decrease its infectivity.<sup>177</sup> FDA advocated such attention to source materials in its four letters, the first of which was issued in 1992 and the last of which were issued in 1994. Thus, at least initially, the actions taken by FDA seem to lag behind the WHO recommendations to reduce the risk of BSE.

The WHO had another consultation about BSE on May 7, 1993, which discussed new scientific information which had become available since the previous meeting and stated that there were indications that the feed ban was having a positive effect.<sup>178</sup> At this time, FDA had sent out the first two of its letters suggesting careful selection of source materials and was conducting its survey of sheep rendering practices to assess the effectiveness of the voluntary ban. This report recommended that although the list of specified offals was not being expanded, these materials “should not enter the human or animal food chains,” giving reference to the memorandum from the 1991 meeting, and stated that evidence increasingly indicated that the infectivity of BSE may be most significant in central nervous system tissue.<sup>179</sup> The report stated that because there was no known case of a naturally occurring TSE in pigs, these animals represent a negligible risk.<sup>180</sup> The report also stated that evidence did not suggest an increase in the number of cases of CJD which could be attributed to the BSE epidemic and referred readers to the 1992 meeting summary for information about reducing risks to humans.<sup>181</sup> Although FDA was still a little slow at this time in implementing the recommendations from the 1991 meeting, they had begun to advise manufacturers to be careful about the source of their materials and to evaluate the effectiveness of the voluntary ban by sheep renderers. However, with the announcement

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<sup>176</sup>See *Public Health Issues Related to Animal and Human Spongiform Encephalopathies: Memorandum from a WHO Meeting*, 70 BULL. OF THE WORLD HEALTH ORG. 183, 187-88 (1992).

<sup>177</sup>See *id.* at 188-90.

<sup>178</sup>See *Bovine Spongiform Encephalopathy in the United Kingdom: Memorandum from a WHO Meeting*, 71 BULL. OF THE WORLD HEALTH ORG. 691, 691-94 (1993).

<sup>179</sup>*Id.* at 692-94.

<sup>180</sup>See *id.*

<sup>181</sup>See *id.*

in 1996 of the possible link between BSE and nv-CJD, pressure to act would soon increase.

In the years between the 1993 meeting and the 1996 announcement, FDA did move to increase efforts to insure the proper sourcing of materials and to propose a ban on using specified sheep offal in ruminant feed. The WHO meeting on April 2-3, 1996, the month after the announcement, set forth some new recommendations. Among these recommendations included the statement that “No part or product of any animal which has shown signs of a TSE should enter any food chain (human or animal),” which meant killing and safely disposing of such animals, reviewing rendering procedures to ascertain how effectively they inactivate the infectious agent, and creating a system of surveillance and notification in order to determine the presence of BSE in the country.<sup>182</sup> Although the report stated that milk, gelatin (if properly manufactured), and tallow (if appropriate rendering practices are used) are safe, it restated the importance of obtaining bovine materials for use in medical products only from countries without BSE and declared that “[a]ll countries should ban the use of ruminant tissues in ruminant feed.”<sup>183</sup> The United States began to take this final step; however, as mentioned previously, the WHO had recommended such a step, at least for specified offals, in 1991, and such a rule was not finalized in the U.S. until 1997.

The WHO held a second meeting in 1996 on May 14-16, in which it focused on nv-CJD. This report announced the possibility of a diagnostic test that uses cerebrospinal fluid and was still being researched.<sup>184</sup> The report from this meeting discussed the clinical signs of nv-CJD and stated that a link between BSE and nv-CJD had not been proven.<sup>185</sup> Other subjects that the experts discussed were the surveillance system for CJD and other TSE’s and the further research that was necessary.<sup>186</sup> Thus, this meeting did not result in

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<sup>182</sup>*Report of a WHO Consultation on Public Health Issues Related to Human and Animal Transmissible Spongiform Encephalopathies*, WHO document, Apr. 2-3, 1996, at 2-3 (last modified Apr. 24, 1998), available in <<http://www.who.int/emc/diseases/bse/bsecjd.html#a1>>.

<sup>183</sup>*Id.* at 3-5.

<sup>184</sup>*See Excerpts from Report of a WHO Consultation on Clinical and Neuropathological Characteristics of the New Variant of CJD and Other Human and Animal Transmissible Spongiform Encephalopathies*, WHO document, May 14-16, 1996, at 4 (last modified Apr. 24, 1998), available in <<http://www.who.int/emc/diseases/bse/may14rep.html>>.

<sup>185</sup>*See id.* at 7-8.

<sup>186</sup>*See id.* at 8-13.

any further recommendations; however, the fact that there was a second meeting served to reemphasize the importance and significance of this problem.

The WHO held another consultation on the subject of TSE's on March 24-26, 1997, just a few months before FDA announced the final rule regarding mammalian to ruminant feeding in the United States. This report covered many of the same topics as the previous ones and added some details about how specific measures were to be performed or what factors should be considered in making assessments.<sup>187</sup> The WHO recognized that there is still debate about the nature of the infectious agent that is causing these TSE's and that a causal relationship between BSE and nv-CJD has not been proven.<sup>188</sup> The report recommended that manufacturers avoid using bovine materials, and materials from other animals with naturally occurring TSE's, in medicinal products and suggested that when this is not possible, manufacturers should carefully select source materials by taking into account numerous factors that could affect their possible contamination with BSE.<sup>189</sup> Other issues covered in this report include the risk of transmission from medical instruments, pituitary hormones, and dura mater used in medical procedures, the risk of transmission from blood, the risk of BSE in sheep, and the risk from food products derived from ruminants.<sup>190</sup> The report expressed some concern about the possible transmission of nv-CJD through blood and recommended excluding donors who have a familial history of these diseases, had received treatments derived from human pituitary glands, or had received a dura mater graft.<sup>191</sup> These policies for blood donation seem generally to have been implemented in the United States by FDA.<sup>192</sup> The report also recommended the vigorous enforcement of any laws implemented to protect the food supply.<sup>193</sup> The previous section indicates that FDA is attempting to

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<sup>187</sup>See *WHO Report 1997*, *supra* note 15, at 1-12.

<sup>188</sup>See *id.* at 5.

<sup>189</sup>See *id.* at 6. These factors included the source of the materials and the BSE status of the country from which they are imported, the type of material, the method used for collecting the materials, procedures to decrease infectivity of the material, the amount of material, and the method used to administer the material. The report also recommended these procedures for cosmetic manufacturers. See *id.* at 6-9.

<sup>190</sup>See *id.* 9-11.

<sup>191</sup>See *id.* at 10.

<sup>192</sup>See discussion *supra* Part V.A.

<sup>193</sup>See *WHO Report 1997*, *supra* note 15, at 11.

do so in this country.

The actions of the United States have been called temperate when compared to those recommended by the WHO.<sup>194</sup> Comparing the actions of FDA with the recommendations of the WHO indicates that although FDA initially may have been slow to implement changes at the time that the WHO recommended them, current regulation in the U.S. appears to fulfill the majority of the WHO's recommended policy. One may also give FDA some leniency because they were trying to assess the particular needs of this country, which could vary from those of other countries. Thus, the WHO recommendations merely serve as a guideline for what the generally accepted ideas and appropriate action were at the time. However, the WHO recommendations have been said to remove some of the doubt as to whether action is necessary and as to what action is necessary.<sup>195</sup> When the ruminant to ruminant feeding ban was suggested in the United States, a representative of FDA said that they were "trying to both complement and expand [the WHO's] recommendation..."<sup>196</sup> The only two major discrepancies seem to be the initial lag in suggesting that manufacturers of products that use bovine materials — not just the manufacturers of dietary supplements — carefully select the origin of their materials, and the amount of time that it took to consider and decide to implement a ruminant to ruminant feed ban. However, FDA seems to have made up for the initial delay by recent actions, and perhaps the initial delay will not result in any harm as there have not yet been any cases of BSE in the United States.

#### D.

On January 7, 1999, the Humane Farming Association, Center for Food Safety (part of the International

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<sup>194</sup>See *1996 Hearing 1*, *supra* note 5, at 114 (statement of Frederick Murphy, School of Veterinary Medicine, Univ. of Calif., Davis).

<sup>195</sup>See *id.* at 124 (statement of Lester M. Crawford, DVM, Ph.D., Assoc. of Am. Veterinary Med. Colleges).

<sup>196</sup>*Id.* at 95 (statement of Michael Friedman, M.D., FDA).

Center for Technology Assessment), the Center for Media and Democracy, and a number of victims or relatives of victims of CJD filed a petition with FDA requesting that FDA amend its final rule to close some loopholes that would allow TSE's to spread within the United States.<sup>197</sup> This petition provides a fourth way of assessing whether the actions of FDA were sufficient to protect the American food supply from TSE's, because it highlights issues about which the consuming public is concerned. I will discuss some of the criticisms mentioned in the petition in this section.

## 1.

The petition requests that the rule be amended to prevent the feeding of blood and blood products to animals.<sup>198</sup> The U.S. regulation of its blood supply was discussed in Part V.A., so I will not elaborate on the subject at length here, but this criticism goes beyond the protection of the blood supply to address the addition of blood products to animal feed, especially for calves. As previously discussed, there is great uncertainty about whether the infectious agent can actually be transmitted via blood. The final rule exempts blood from the definition of protein derived from mammalian tissues.<sup>199</sup> Despite evidence that low levels of the infectious agent may sometimes be present in blood,<sup>200</sup> it has not been shown to transmit the disease and has been considered safe in the WHO recommendations.<sup>201</sup> Thus, this is a subject about which reasonable people can differ in opinion. The petitioners view this as a risk that needs to be eliminated. However, although some may think that a ban on using blood products for animal feed is necessary, as long as the

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<sup>197</sup>See *FDA Petition*, *supra* note 1.

<sup>198</sup>See *FDA Petition*, *supra* note 1.

<sup>199</sup>See Animal Proteins Prohibited in Ruminant Feed (Final Rule), 62 Fed. Reg. 30936, 30976 (1997) (codified at 21 C.F.R. 589).

<sup>200</sup>See *1997 Hearing*, *supra* note 3, at 81 (Clarence J. Gibbs, Ph.D., NIH).

<sup>201</sup>See Animal Proteins Prohibited in Ruminant Feed, 62 Fed. Reg. 551, 561 (1997) (to be codified at 21 C.F.R. pt. 589.2000) (proposed Jan. 3, 1997).



blood is not contaminated from other, more dangerous, parts of the animal, FDA should not be denounced for not having prohibited the use of blood products as well.

## 2.

Gelatin is also exempted from the definition of protein derived from mammalian tissues.<sup>202</sup> The petition requests that this exemption be removed so that gelatin is not fed to animals, especially considering that high risk material can be introduced into the gelatin if whole bones, such as vertebrae are used to manufacture it.<sup>203</sup> In 1994, preliminary data that the gelatin industry presented to FDA was the basis for FDA's 1994 decision to exempt gelatin from its recommendations for products containing bovine ingredients from countries where BSE is present.<sup>204</sup> Additionally, the WHO has declared that gelatin is safe as long as the source materials are not contaminated with TSE's and the manufacturing process has been shown to eliminate or inactivate any TSE infectivity.<sup>205</sup> However, recently, the TSE Advisory Committee determined that current information no longer warranted such an exemption.<sup>206</sup> As a result, FDA issued a Level 1 guidance on which it will be accepting comments but which will be implemented immediately due to the risk to public health.<sup>207</sup> The guidance lists recommendations for choosing materials from which to make gelatin.<sup>208</sup> This does not address the use of gelatin in animal feed, though. However, the appendix to the guidance does state that

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<sup>202</sup>See Animal Proteins Prohibited in Ruminant Feed (Final Rule), 62 Fed. Reg. 30936, 30976 (1997) (codified at 21 C.F.R. 589).

<sup>203</sup>See *FDA Petition*, *supra* note 1.

<sup>204</sup>See Guidance for Industry on the Sourcing and Processing of Gelatin to Reduce Potential Risk, 62 Fed. Reg. 52345 (1997)(notice of availability Oct. 7, 1997).

<sup>205</sup>See *WHO Report 1997*, *supra* note 15, at 7.

<sup>206</sup>See Guidance for Industry on the Sourcing and Processing of Gelatin to Reduce Potential Risk, 62 Fed. Reg. 52345 (1997)(notice of availability Oct. 7, 1997).

<sup>207</sup>See FDA, *Guidance for Industry: The Sourcing and Processing of Gelatin to Reduce the Potential Risk Posed by Bovine Spongiform Encephalopathy (BSE) in FDA-Regulated Products for Human Use*, Sept. 1997, at 1, available in <<http://www.fda.gov/opacom/morechoices/industry/guidance/gelguide.htm>>.

<sup>208</sup>See *id.* at 3-4.

it is actually only domestic gelatin that is exempted from the rule because gelatin is not generally added to animal feed as a protein supplement and bovine-derived products (including gelatin) that are imported from countries where BSE is found are banned by USDA.<sup>209</sup> Thus, FDA does not seem to be ignoring the possible risk from gelatin and has revised its policy as it receives new scientific information about the substance.

### 3.

Another area of controversy surrounds the fact that porcine meat was excluded from the final rule because pigs are often slaughtered at facilities that produce pure porcine material and have never been shown to have a naturally occurring TSE.<sup>210</sup> However, the final rule does admit that there is some scientific evidence suggesting that pigs can deliberately be infected with TSE.<sup>211</sup> Experiments have shown that intracerebral inoculation can transmit BSE to pigs, but it is not known whether the disease can be transmitted orally.<sup>212</sup> Despite this evidence, the WHO considers the risk of transmitting a TSE through food from pigs to be negligible.<sup>213</sup> The Consumer's Union also has criticized the final rule for failing to include pigs in the prohibited material.<sup>214</sup> There has even been one instance of a veterinarian who reports having examined pigs with symptoms matching those of a TSE in the 1970s.<sup>215</sup> Concern arises about the idea that if such a TSE does exist in pigs or can be transmitted to them, the final rule would not prevent amplification of the disease through the recycling of pig protein to ruminant animals through feed. This seems to be an area in which

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<sup>209</sup> See *id.* at 5.

<sup>210</sup> See Animal Proteins Prohibited in Ruminant Feed (Final Rule), 62 Fed. Reg. 30936, 30943-44 (1997) (codified at 21 C.F.R. 589); See CVM, A Report on the Questions Asked and Answered on the Air During the June 24 BSE Satellite Teleconference 30 <<http://www.fda.gov/cvm/fda/TOCs/bsetrans.html>>.

<sup>211</sup> See Animal Proteins Prohibited in Ruminant Feed (Final Rule), 62 Fed. Reg. at 30939.

<sup>212</sup> See 1997 Hearing, *supra* note 3, at 82-83 (Clarence J. Gibbs, Ph.D., NIH).

<sup>213</sup> See *Bovine Spongiform Encephalopathy in the United Kingdom: Memorandum from a WHO Meeting*, 71 BULL. OF THE WORLD HEALTH ORG. 691, 694 (1993).

<sup>214</sup> See SHELDON RAMPTON & JOHN STAUBER, MAD COW U.S.A. 216 (1997).

<sup>215</sup> See *id.* at 212-15.

further investigation is necessary. If it is possible to transmit BSE to pigs intracerebrally, it might be possible to do so orally, and the petitioners could have a viable claim in their request that protein derived from pigs should be excluded from animal feed. This area could theoretically present a large loophole in the regulation.

#### 4.

Because of the fact that the presence of one animal infected with a TSE can amplify the disease if that animal is rendered and introduced into animal feed, the petitioners also request that no part of an animal that is showing signs of a TSE be allowed in animal feed and that this material be prohibited from fertilizer, cosmetics, and other products as well.<sup>216</sup> This suggestion is more of a general prophylactic rule to prevent any TSE from entering the food chain (as recommended by the WHO).<sup>217</sup> It is difficult to assess whether this criticism indicates that FDA has not adequately performed its job because it is based more on theory and conjecture than on proven science. However, the National Pork Producers Council commented that they would support a rule prohibiting the introduction of any species known to have a TSE into livestock feed.<sup>218</sup> Due to the fact that the species barriers between TSE's are unpredictable, it seems logical that animals that are suspected of having TSE and all tissues derived from them, whether they are exempted from the regulation or not, should not be allowed to enter the food chain. When an animal is suspected of having the disease, this should increase the risk and alert us to use extra caution. This amendment to the rule requests that we err on the side of safety in these cases.

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<sup>216</sup>See *FDA Petition*, *supra* note 1.

<sup>217</sup>See *FDA Petition*, *supra* note 1.

<sup>218</sup>See *Public Meeting 2*, *supra* note 2, at 47.

## 5.

Petitioners also want to extend the length of time that records must be kept from one year to ten years because animals will not show signs of a TSE during a one year time period and because keeping the records for a longer period of time will establish a method for determining the origin of contaminated material.<sup>219</sup> FDA actually decreased the recordkeeping requirement from two years to one year.<sup>220</sup> However, the petitioner's request seems to be based on a misunderstanding of the reasons for which FDA is requiring the records. Records will be used during inspection and to trace animal feed backwards and forwards through the distribution chain in order to insure that prohibited material is not being fed to the wrong animals.<sup>221</sup> The records could also be used to notify customers if a problem is found, but there is not much practical value to requiring that the records be kept for a longer period of time because the long and often unknown incubation period for the disease would make it difficult to determine its source.<sup>222</sup> Thus, it seems that determining the source of contamination years later will be almost impossible because the period of infection cannot even be pinpointed exactly. The records are being used for the more immediate purposes of facilitating inspection to document compliance with the rule. Thus, although difference of opinion obviously exists on this matter, this does not seem to be an area where FDA is not accomplishing its goals of protecting the food supply.

## E.

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<sup>219</sup>See *FDA Petition*, *supra* note 1.

<sup>220</sup>See Animal Proteins Prohibited in Ruminant Feed (Final Rule), 62 Fed. Reg. 30936, 30955 (1997) (codified at 21 C.F.R. 589).

<sup>221</sup>See CVM, A Report on the Questions Asked and Answered on the Air During the June 24 BSE Satellite Teleconference 9, 14 <<http://www.fda.gov/cvm/fda/TOCs/bsetrans.html>>.

<sup>222</sup>See *id.* at 31.

There are numerous other areas about which people are concerned because they fear that BSE or another TSE could infiltrate our food chain. Concerns about medical products were discussed in Part V.C. because the WHO has made recommendations on this issue. Additionally, FDA has recently issued a guidance on this issue, which contains recommendations for the manufacturers of medical products derived from both bovine and other sources and suggests areas in which FDA is considering implementing other changes as well.<sup>223</sup> This is another guidance about which FDA is accepting comments but which it is implementing immediately due to concerns about the public health.

People have also expressed concern about milk products, but, as mentioned above, numerous institutions have suggested that milk products are safe. In fact, scientists were not able to detect any infectivity in the milk of nursing mothers who had kuru or in mammary gland tissues or milk from cattle that had been diagnosed with BSE.<sup>224</sup>

One final concern, although there are numerous others that could be listed, is tallow. One comment to the final rule suggested that the proposed rule really did not take any action because it still allowed the use of tallow in ruminant feed.<sup>225</sup> Tallow is excluded from the final rule because it is not a proteinaceous material, and FDA notes that infectivity studies suggest that these are low risk materials.<sup>226</sup> However, if there is risk involved, perhaps the exclusion is not warranted. This is another topic of debate.

## VI. Conclusion

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<sup>223</sup> See FDA, *Guidance for FDA Reviewers and Industry: Medical Devices Containing Materials Derived from Animal Sources (Except for In Vitro Diagnostic Devices)*, Nov. 6, 1998.

<sup>224</sup> See 1997 Hearing, *supra* note 3, at 82 (Clarence J. Gibbs, Ph.D., NIH).

<sup>225</sup> See Animal Proteins Prohibited in Ruminant Feed (Final Rule), 62 Fed. Reg. 30936, 30944-45 (1997) (codified at 21 C.F.R. 589).

<sup>226</sup> See *id.* at 30938.

Perceptions about the significance of mad cow disease range from comforting reassurances that our food supply is safe and that there has never been a case of BSE found in the United States to the apocalyptic image conveyed by Carleton Gajdusek, which ends with a statement that sums up the issue for each question that is raised: “That hasn’t been excluded either.”<sup>227</sup> In front of the British Parliament, Richard Lacey said that merely reassuring the public by monitoring the incidence of CJD is a huge experiment and that he could not believe that a scientist would say “In order to find out how big the problem is we are going to see how many people die.”<sup>228</sup> The questions that always arise are whether to act or not and whether to act now or later.

I compared FDA’s actions with the lessons that it should have learned from previous mistakes in order to determine whether improvement has been made, with its own goals for enforcement in order to assess how well it is achieving results from the actions that it decided to take and whether there are flaws in the rule, with the WHO guidelines in order to consider whether FDA acted in a manner reasonable given the general scientific and political opinion of the situation at the time, and with a recent petition to FDA in order to consider whether the general public thinks that FDA’s actions were stringent enough. With the major exception of failing to consider or implement a ban on feeding specified offals to ruminants until the posited link between BSE and nv-CJD was announced in 1996, all of these assessments lead to the conclusion that FDA acted reasonably and efficiently to protect the American food supply.

Of course, it will not be possible to determine if this is true or not until it may be too late. There is no way to know what amount of action is sufficient. But given all of these methods of assessment, at the very least one can say that FDA’s actions seem reasonable in the given circumstances. One can always ask why they didn’t do more or didn’t do something faster, but FDA appears to have generally acted with sufficient speed to protect the American public. Of course, it is easier to make that assertion since BSE did not spread to or

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<sup>227</sup>Richard Rhodes, *Deadly Feasts* 220-21 (1997).

<sup>228</sup>*Id.* at 187 (1997).

occur in the United States during the period in which FDA may not have acted as quickly as it could have. One can only hope that analysis of the relevant indications led FDA to act as it did and that if the situation was different — BSE was going to be found in this country — that there would have been indications that would have led FDA to act differently.

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